

Application No.: 09/391,762
Amendment and Response filed on April 11, 2005
Reply to Office Action of November 10, 2004
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REMARKS

Reconsideration of the application as amended is respectfully requested.

Status of the Claims

Claims 1-4, 7, and 9-31 are currently pending in this application. Claims 13, 28, and 31 are being presented herein in amended form from their previously presented form. Claims 1-4, 7, 9-12, and 14-20 have been previously amended and are re-presented herein in their previously amended form. New claims 21-27 and 29-30 are being re-presented herein. Claims 5-6 and 8 have been previously cancelled.

Discussion of the Amendments to the Claims

The claims have been amended to point out more particularly and to claim more distinctly the subject invention. In particular, claim 13 has been amended to insert the word "wherein" before the phrase "said biodegradable composition" and to insert the phrase "capable of" before the word "forming." Claim 28 has been amended to recite that the solution is pH-adjusted to a pH of about 7.4 to form an insoluble substrate site for cellular attachment. Claim 31 has been amended to change "crosslinked" to "crosslinkable." These amendments are all non-narrowing in scope. Support for the amendments to the claims can be found in the instant specification at, for example, col. 2, lines 61-67, col. 3, lines 1-6 and 64-67, col. 4, lines 64-66, and at col. 6, lines 11-13. No new matter has been added by way of the amendments to the claims.

Response to the Claim Objections with Regard to Claims 13 and 31

The Examiner has objected to claims 13 and 31. In particular, the Examiner alleges that claim 13 appears to be "claiming both the intermediate product and the final product so it is unclear which is relevant." (Office Action, page 2). Moreover, with regard to claim 31, the

Examiner alleges that the use of the term “crosslinked” is confusing since the intermediate product is being set forth.” *Id.*

Applicants have amended claim 13 to insert the language “capable of” before “forming” as suggested by the Examiner. Moreover, Applicants have amended claim 31 to change “crosslinked” to “crosslinkable” as suggested by the Examiner. Accordingly, Applicants submit that the basis for the objections is moot and respectfully request withdrawal of the objections.

Response to the 35 U.S.C. § 112, Second Paragraph Rejection

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the subject matter of the invention. In particular, the Examiner alleges the following: “Claim 28 contradicts base claim 13 that requires an acidic solution, yet the present claims attempts [sic] to claim a pH-adjusted solution.” (Office Action, page 3). Applicants respectfully traverse the rejection.

As amended, claim 13 is directed to an implantable prosthesis that includes a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between the nodes and fibrils, wherein a solution of a biodegradable composition having an acidic pH is contained within the pores, and wherein the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. Moreover, claim 28, as amended herein, now recites that the solution is pH-adjusted to a pH of about 7.4 to form an insoluble substrate site for cellular attachment. In view of these amendments, it is respectfully submitted that the basis for the rejection under 35 U.S.C. § 112, second paragraph, is moot. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

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Response to the Rejection under 35 U.S.C § 251

Claims 1-4, 7, and 9-31 stand rejected under 35 U.S.C. § 251 as allegedly being an improper recapture of broadened subject matter surrendered in the application for the patent upon which the present reissue is based. Specifically, the Examiner states that during the pendency of U.S. Application Serial No. 08/289,790, which issued as U.S. Patent No. 5,665,114, the following limitations were added to overcome a prior art rejection: “filled with [a] fluid which solidifies and is crosslinked to form” and “said material being insoluble at a pH of about 7.4.” (Office Action, pages 3-4). The Examiner then concludes that Applicants are improperly attempting to recapture subject matter previously surrendered. The rejection under 35 U.S.C. § 251 is respectfully traversed.

It is well-settled that the doctrine of recapture estoppel bars a patentee from acquiring reissue claims that are of the same or of broader scope than those claims that were cancelled from the original application. *Ball Corp. v. United States*, 221 U.S.P.Q. 289 (Fed. Cir. 1984). However, it also is well-settled that a patentee is free to acquire, by reissue, claims that are narrower in scope than the cancelled original claims without violating the recapture doctrine. *Whitaker Corp. v. UNR Industries, Inc.*, U.S.P.Q.2d 1742 (Fed. Cir. 1990). Reissue claims that are broader in certain respects but narrower in other respects may avoid the effect of the recapture doctrine. A patentee can, therefore, obtain a reissue claim where that claim varies materially from the claim originally surrendered, even where it omits a limitation added during prosecution. *Donald S. Chisolm, Chisolm on Patents*, §15.03 [2] [e] (1999).

Original claim 1, which was subsequently amended to include limitations mentioned by the Examiner, recited the following:

An implantable member for use in repair or replacement with a body comprising an expanded polytetrafluoroethylene surface having pores present in its

wall structure wherein said pores contain a solid insoluble biocompatible, biodegradable material of natural origin.

Applicants do not dispute that the limitations “filled with a fluid which solidifies and is crosslinked to form” and “said material being insoluble at a pH of about 7.4” were specifically added to original claim 1 during prosecution. However, as discussed below, presently pending claims 1-4, 7, and 9-31 do not attempt to recapture subject matter previously surrendered.

Discussion of Claims 1-4, 7, 9-12, 22-23, and 26

Presently pending claim 1 recites the following:

An implantable member for use in repair or replacement within a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils, said pores filled with a solid precipitate of a material of natural origin formed in situ from a solution that is pH-adjusted within said pores.

As highlighted above, presently pending claim 1 contains the limitation that the pores are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. Clearly, presently pending claim 1 is materially different from claim 1, as originally presented in the prior application, which does not contain such a limitation. Moreover, as claims 2-4, 7, 9-12, 22-23, and 26 depend from claim 1 (either directly or indirectly), those claims also are materially different from claim 1 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 1-4, 7, 9-12, 22-23, and 26 are properly submitted in the reissue application.

Discussion of Claims 13-20 and 28

Presently pending claim 13, as amended herein, recites the following:

An implantable prosthesis comprising a body of expanded polytetrafluoroethylene having a structure of spaced apart nodes interconnected by fibrils with pores present between said nodes and said fibrils, wherein a solution of a biodegradable composition having an acidic pH is contained within said pores, wherein said biodegradable composition is capable of forming a precipitate that substantially fills said pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment.

As highlighted above, presently pending claim 13, as amended herein, contains the limitation that the pores contain a solution of a biodegradable composition having an acidic pH. Moreover, amended claim 13 contains the limitation that the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. In view of these limitations, presently pending claim 13, as amended herein, is materially different from claim 1 as originally presented in the prior application. As claims 14-20 and 28 depend from claim 13 (either directly or indirectly), those claims also are materially different from claim 13 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 13-20 and 28 are properly submitted in the reissue application.

Discussion of Claims 21, 24-25, and 27

Presently pending claim 21 recites the following:

An implantable member for use in repair or replacement within a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils with pores present between said nodes and said fibrils, said pores substantially filled with a solid precipitate of a material of natural origin formed in situ from a solution that is pH-adjusted within said pores.

As highlighted above, presently pending claim 21 contains the limitation that the pores are substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within said pores. In view of this limitation, presently pending claim 21 is materially different from claim 1 as originally presented in the prior application. As claims 24-25 and 27 depend (either directly or indirectly) from claim 21, those claims also are materially different from claim 1 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 21, 24-25, and 27 are properly submitted in the reissue application.

Discussion of Claims 29-31

Presently pending claim 29 recites the following:

An *intermediate* implantable member for use in repair or replacement within a body comprising an expanded polytetrafluoroethylene substrate having a wall structure including nodes and fibrils, with pores present between said nodes and said fibrils, said pores filled with an acidic fluid.

As highlighted above, pending claim 29 recites an intermediate implantable member having pores that are filled with an acidic fluid. In view of this recitation, presently pending claim 29 is materially different from claim 1 as originally presented in the prior application. As claims 30-31 are dependent upon claim 29 (either directly or indirectly), those claims also are materially different from claim 1 as originally presented in the prior application. Accordingly, the recapture estoppel doctrine does not apply, and claims 29-31 are properly submitted in the reissue application.

In view of the foregoing, the recapture doctrine is inapplicable in the case at hand. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 251.

Discussion of the 35 U.S.C. § 102(b) Rejection

Claims 1-4, 7, 13-17, 21-25, and 29-31 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Kaehler et al., *Journal of Vascular Surgery*, 9(4) (April 1989) (hereinafter "Kaehler"). In particular, the Office alleges that Kaehler describes a vascular graft that has a structure of spaced apart nodes interconnected by fibrils with pores present between the nodes and fibrils. (Office Action, page 4). In particular, the Office alleges the following:

On page 536, Kaehler teaches filling the graft with an acidic solution containing collagens I, III, and IV; see the forth [sic] full paragraph of the right column. The 0.05 N HCl solution has a pH of 2.0; see CRC handbook of Chemistry and Physics, 64th Edition (1984), page D-151. After the pores are filled with the 2.0 pH solution of collagen, the graft is rinsed with water and PBS (i.e., phosphate buffered saline) to remove the acid which inherently changes the pH to near neutral (pH 7.0) since the acid has been removed.

The rejection under 35 U.S.C. §102(b) is respectfully reversed for the reasons set forth below.

To support a rejection under 35 U.S.C. § 102(b), a reference must disclose each and every element of the claimed invention. The Examiner has failed, however, to make this requisite showing.

Contrary to the Examiner's contention, the fourth full paragraph at the right-hand column of Kaehler on page 536 does not disclose filling the pores of a graft with an acidic solution containing collagen types I, III, and IV. Rather, one of ordinary skill in the art would appreciate that the 1 ml 0.05 N HCl solution only contains collagen type IV and is applied to the inner surface of a graft that was already precoated with collagen types I and III. (See Declaration of Gary Loomis, ¶¶15-17). In other words, Kaehler discloses first precoating the graft disclosed therein with collagen types I and III using the procedure set forth at the first full paragraph of the right-hand column on page 536 and then applying a second coating over the precoating by filling the graft with an acidic solution that contains a very small amount of collagen type IV and subsequently air-drying that acidic solution. (See Declaration of Gary

Loomis, ¶¶15-16). There is absolutely no disclosure whatsoever of filling the pores with an acidic solution. (See Declaration of Gary Loomis, ¶17). Indeed, the collagen types I and III precoating would prevent the acidic solution from ever reaching the pores of the graft disclosed in Kaehler. (See *id.*). In fact, Kaehler explicitly states that the collagen types I and III mixture “completely covered the underlying PTFE material” as a “densely woven mat.” (Kaehler, page 537, paragraph bridging the columns). In view of this disclosure, one of ordinary skill in the art would readily understand that the HCl solution referenced by the Examiner would never reach the pores of the PTFE graft of Kaehler (See Declaration of Gary Loomis, ¶17).

For the reasons discussed above, it cannot be said that Kaehler discloses an implantable member where the pores in an expanded polytetrafluoroethylene substrate are filled with an acidic solution (as required by claims 29-31). (See Declaration of Gary Loomis, ¶17). Moreover, it cannot be said that Kaehler discloses an implantable prosthesis where a solution of a biodegradable composition having an acidic pH is contained within the pores and is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment (as now required by pending claims 13-17). (See Declaration of Gary Loomis, ¶17). Accordingly, Applicants respectfully submit that the anticipation rejection with regard to claims 13-17 and 29-31 is improper.

As regards pending claims 1-4, 7, and 22-23, those claims all require an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted **within the pores**. Pending claims 21 and 24-25, meanwhile, all require an implantable member where the pores are substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted **within the pores**. Kaehler, however, is not directed to precipitating a material of natural origin within the pores of a graft by means of pH-adjustment. Rather, Kaehler is directed to ascertaining optimal precoating substrates for the endothelial cell lining of PTFE grafts. (See Kaehler, abstract; see also Declaration of Gary Loomis, ¶7). To that end, Kaehler discloses applying a collagen

solution having a pH of 7.2 to a PTFE graft and subsequently heating and drying the graft. (See Kaehler, page 536; see also Declaration of Gary Loomis, ¶7). As previously submitted (see Applicants' Amendment and Response to Office Action filed on April 21, 2004), Kaehler merely discloses adjusting the pH of the collagen solution to 7.2 prior to applying the solution to the graft. (See Kaehler, page 536; see also Declaration of Gary Loomis, ¶7). There is no disclosure of adjusting the pH of a solution within the pores to form a solid precipitate of a material of natural origin therein, as would be readily appreciated by one of ordinary skill in the art. (See Declaration of Gary Loomis, ¶17).

Moreover, the disclosure of Kaehler would not lead one of ordinary skill in the art to conclude that a solid precipitate of natural origin fills or substantially fills the pores of the PTFE graft disclosed therein. (See Declaration of Gary Loomis, ¶¶7 and 13). In fact, although Kaehler discusses "interstices filling matrices" (page 537, paragraph bridging the columns), there is no evidence presented in Kaehler that a solid precipitate of a material of natural origin fills or substantially fills the pores of the PTFE graft.¹ (See Declaration of Gary Loomis, ¶13). In particular, the SEM data discussed in Kaehler does not indicate that the pores are filled with a precipitate. (See Declaration of Gary Loomis, ¶13). Indeed, Kaehler's disclosure that the collagen type I/III mixture "completely covered the underlying PTFE material" as a "densely woven mat" (Kaehler, page 537, paragraph bridging the columns) would lead one of ordinary skill in the art to believe that the graft is merely coated with collagen types I and III, in accordance with Kaehler's discussion of a precoating. (See Declaration of Gary Loomis, ¶13).

Notwithstanding the foregoing, the Board of Patent Appeals and Interferences and the Examiner have previously contended that solidified or precipitated collagen is present

¹One of ordinary skill in the art would not necessarily conclude that the pores were filled merely in view of the disclosure of "interstices filling matrices" at page 537. Indeed, as physicians, the authors of the Kaehler reference may have ascribed a meaning to the phrase "interstices filling matrices" that is different than the meaning that would be ascribed to that phrase by a polymer chemist skilled in the art of making PTFE grafts. (See Declaration of Gary Loomis, ¶¶13 and 19).

within the pores of the graft because “Kaehler reports that it was ‘almost impossible to force the solution through the graft’ at the end of the third procedure.” (See Decision on Appeal mailed on July 21, 2003, paragraph bridging pages 9-10; see also Office Action mailed on November 21, 2003 (incorporating by reference the rejections rendered by the Board of Appeals and Interferences)). However, in view of the experimental design set forth at the third full paragraph of page 536 (left-hand column), and the overall disclosure of Kaehler, one of ordinary skill in the art would not reach this conclusion. (See Declaration of Gary Loomis, ¶¶ 9 and 11-12). Rather, in view of the aforementioned disclosure, one of ordinary skill in the art would readily surmise that a suspension or slurry of collagen was merely introduced into the lumen of a clamped graft until it became difficult or impossible to do so.² (See Declaration of Gary Loomis, ¶¶ 8-11). In particular, one of ordinary skill in the art would surmise that air would have been displaced out of the pores of the graft upon the initial introduction of the collagen suspension or slurry into the lumen of the graft. (See Declaration of Gary Loomis, ¶10). Moreover, one of ordinary skill in the art also would surmise that as a result of the inner surface of the graft becoming coated with collagen, air could no longer be forced through the pores, thereby rendering it increasingly difficult to inject the suspension or slurry of collagen into the graft lumen. (See *id.*). Thus, to clarify remarks of record, one of ordinary skill in the art would appreciate that Kaehler, most likely, was merely forcing the contents of the syringe into the lumen of the clamped graft and not into the graft interstices. (See Declaration of Gary Loomis, ¶11). Indeed, if the collagen suspension or slurry was truly being “forced” into the graft interstices, then one of ordinary skill in the art would expect that collagen would be present on both the inner and outer surfaces of the graft. (See Declaration of Gary Loomis, ¶12). There is no indication in Kaehler, however, that such is the case.

As Kaehler fails to disclose each and every element of the invention recited in claims 1-4, 7, 13-17, 21-25, and 29-31, Kaehler cannot be said to anticipate those claims. Accordingly,

² While Kaehler states that a “collagen solution” having a pH of 7.2 was used, one of ordinary skill in the art would understand that a collagen suspension or slurry, and not a collagen solution, would have been formed at a pH range of 7.2. (See Declaration of Gary Loomis, ¶8).

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Applicants respectfully submit that the rejection under 35 U.S.C. § 102(b) is improper and should be withdrawn.

Discussion of the 35 U.S.C. § 103(a) Rejection Over Kaehler in View of the Hoffman '977 Patent

Claims 9-10 and 19-20 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kaehler in view of U.S. Patent No. 5,197,977 (hereinafter "the Hoffman '977 patent"). In particular, the Examiner predicates the rejection on the alleged teaching of Kaehler as set forth by the Examiner with regard to the rejection under 35 U.S.C. § 102(b). Although the Examiner acknowledges that Kaehler fails to disclose the use of a pharmacological agent as claimed, the Examiner nevertheless contends that it would have been obvious to include a pharmacological agent in the Kaehler implant in view of the Hoffman '977 patent. For the reasons set forth below, this rejection is traversed.

As claim 9 depends directly from claim 1, and as claim 10 depends from claim 9, those claims are both directed to an implantable member having pores that are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. However, as discussed above with respect to the rejection under 35 U.S.C. § 102(b), there is no disclosure in Kaehler of precipitating a material of natural origin out of a solution *in situ* by means of pH-adjustment of the solution within the pores. Nor is there any teaching or suggestion in Kaehler of precipitating a material of natural origin out of a solution *in situ* by means of pH-adjustment of the solution within the pores. (See Declaration of Gary Loomis, ¶19). Indeed, Kaehler teaches away from doing the same as Kaehler is merely concerned with coating the surfaces of PTFE grafts and actually discloses adjusting the pH of the collagen solution referenced therein prior to application of the solution onto the graft. (See Declaration of Gary Loomis, ¶7).

The Hoffman '977 patent was cited merely for its disclosure of pharmacological agents. The Hoffman '977 patent nowhere discloses, teaches or suggests an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores of the graft. (See Declaration of Gary Loomis, ¶19). Therefore, the Hoffman '977 patent fails to cure the deficiencies of Kaehler. Moreover, in view of the fact that the Hoffman '977 patent is directed to textile grafts and not PTFE grafts, one of ordinary skill in the art would not even be motivated to combine the disclosure of the Hoffman '977 patent with the disclosure of the Kaehler reference. (See *id.*). In view of the foregoing, claims 9 and 10 are not obvious in view of the teachings of Kaehler in combination with the Hoffman '977 patent. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection based on this combination of references.

Discussion of the 35 U.S.C. § 103(a) Rejection Over Kaehler in View of Tran

Claims 11 and 12 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kaehler in view of Tran and Walt, *Journal of Colloid and Interface Science*, 132(2) (October 15, 1989) (hereinafter "Tran"). In particular, the Examiner predicates the rejection on the alleged teaching of Kaehler as set forth by the Examiner with regard to the rejection under 35 U.S.C. § 102(b). Although the Examiner acknowledges that Kaehler fails to teach modifying a substrate to enhance its hydrophilic character by subjecting the polytetrafluoroethylene to plasma deposition, the Examiner nevertheless contends that it would have obvious to use plasma deposition to pretreat the graft of Kaehler. For the reasons set forth below, this rejection is traversed.

As claim 11 depends directly from claim 1, and as claim 12 depends from claim 11, those claims are directed to an implantable member having pores that are filled with a solid

precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. However, as discussed above, Kaehler fails to disclose an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores of the graft. Nor is there a teaching or suggestion to do so. (See Declaration of Gary Loomis, ¶7). Indeed, as discussed above, Kaehler is merely concerned with coating the surfaces of PTFE grafts and actually discloses adjusting the pH of the collagen solution referenced therein prior to application of the collagen solution onto the graft. (See *id.*). As such, Kaehler actually teaches away from precipitating a material of natural origin within the pores of a graft.

Tran was cited only for its disclosure with regard to plasma deposition. Tran nowhere discloses, teaches or suggests an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores of the graft. (See *id.*). Therefore, Tran fails to cure the deficiencies of Kaehler as a reference. In view of the foregoing, claims 11 and 12 are not obvious in view of the teachings of Kaehler in combination with Tran. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection based on this combination of references.

Discussion of the 35 U.S.C. § 103(a) Rejection Over Kaehler in View of Alonso

Claims 18 and 26-28 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kaehler et al. in view of U.S. Patent No. 5,037,377 (hereinafter "Alonso"). In particular, the Examiner predicates the rejection on the alleged teaching of Kaehler as set forth by the Examiner with regard to the rejection under 35 U.S.C. § 102(b). Although the Examiner acknowledges that Kaehler fails to teach the pH of the phosphate buffer as claimed, the

Examiner nevertheless contends that it would have been obvious to use a phosphate buffer having a pH of 7.4 in view of the Alonso reference.

As claim 18 depends indirectly from amended claim 13, and as claim 28 depends directly from claim 13, those claims are both directed to an implantable prosthesis that includes a body of expanded polytetrafluoroethylene having pores that contain a solution of a biodegradable composition having an acidic pH, wherein the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. Moreover, as claim 26 depends directly from claim 1, claim 26 is directed to an implantable member having pores that are filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. Furthermore, as claim 27 depends directly from claim 21, claim 27 is directed to an implantable member where the pores of an expanded polytetrafluoroethylene substrate are substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores.

However, as discussed above, there is no disclosure, teaching or suggestion in Kaehler of an implantable prosthesis that includes pores that contain a solution of a biodegradable composition having an acidic pH, wherein the biodegradable composition is capable of forming a precipitate that substantially fills the pores at selected conditions of temperature and pH to form an insoluble substrate site for cellular attachment. (See Declaration of Gary Loomis, ¶17). Moreover, as further discussed above, there is no disclosure or suggestion in Kaehler of an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled or substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. (See Declaration of Gary Loomis, ¶¶ 7 and 13).

Alonso was merely cited for its disclosure with regard to phosphate buffer. There is no disclosure, teaching or suggestion in Alonso, however, of an implantable prosthesis where the

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pores of an expanded polytetrafluoroethylene substrate contain a biodegradable composition having an acidic pH, much less a disclosure, teaching or suggestion of such an implantable prosthesis where such a biodegradable composition is capable of forming a precipitate at selected conditions of temperature and pH to form an insoluble substrate for cellular attachment. Moreover, there is no disclosure, teaching or suggestion in Alonso of an implantable member where the pores of an expanded polytetrafluoroethylene substrate are filled or substantially filled with a solid precipitate of a material of natural origin formed *in situ* from a solution that is pH-adjusted within the pores. (See Declaration of Gary Loomis, ¶19). Therefore, Alonso fails to cure the deficiencies of Kaehler as a reference.

In view of the foregoing, claims 18 and 26-28 are not obvious in view of the teachings of Kaehler in combination with Alonso. Accordingly, Applicants respectfully request withdrawal of the Section 103 rejection based on this combination of references.

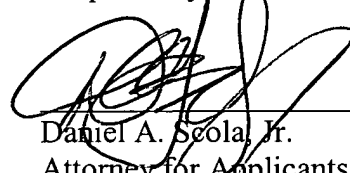
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Concluding Remarks

The claims are believed to be allowable over the art and the application in good and proper form for allowance. The Examiner is invited to contact the undersigned if he has any questions regarding this submission or, if in his opinion, a teleconference call would expedite prosecution of the subject application.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461.

Respectfully submitted,



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